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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,135	05/31/2001	Brandon James Yoe	50623.00168	1923

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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	**PAPER NUMBER**
3772	

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12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/872,135	YOE ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,10-15,17-25,27-32,37-39,41-44,46-50,53-59,61 and 63-82* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,10-12,21-25, 27-32,63-68, 73,and 77-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 13-20,26,37-39,41-44,46-50,53-59,61,69-72,74-76 and 80-82.

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 8/17/2007. No claim has been amended.

Applicant's comments pertaining to the previous Office Action, particularly to the Hossainy et al reference, are acknowledged. Thus, such rejection has been withdrawn.

Claims 13-15, 17-20, 37-39, 41-44, 65, 66, 70, 74, 78, 81 indicated in the previous Office Action as allowable have been regrettably withdrawn.

The claims have been carefully considered but deemed not allowable in view of the following rejection(s).

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 5-7, 10-12, 21-25, 27-32, 63-68, 73, 77-79 drawn to stents, classified in class 600, subclass 3.

II. Claims 13-15, 17-20, 37-39, 41-44, 53-59, 61, 69-72, 74, 76, 80-82 drawn to methods of coating , classified in class 427, subclass 2.24.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

another and materially different process. (MPEP § 806.05(e)). In this case, the methods of Group II may be performed by an apparatus other than the apparatuses of Group I such as the one that would not require the apparatus to deliver a therapeutic agent to a vessel. Likewise, the devices of Group I may be used to perform in a method other than the methods of Group II such one that would require the method utilizing the device to deliver a therapeutic agent to a vessel.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. James Reed on November 28, 2007, a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 3, 5-7, 10-12, 21-25, 27-32, 63-68, 73, and 77-79. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-15, 17-20, 37-39, 41-44, 53-59, 61, 69-72,

74, 76, 79-82 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 21, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 21, 31, the limitation "a point inward" is indefinite since "a point", as claimed, does not define a measurement. The limitations "near the proximal end" and "near the distal end" is indefinite, the term "near" is relative.

Regarding claim 6, the limitation "near" is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 3, 63, 64, 67, and 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Turnlund et al (Patent No. 6,296,603. Turnlund et al discloses in Figures 3 a conventional stent-graft delivery system (28) comprising a radioisotope stent-graft (23) with a stent (20), the stent (20) comprising a central region (21), a proximal region (40), and a distal region (41).

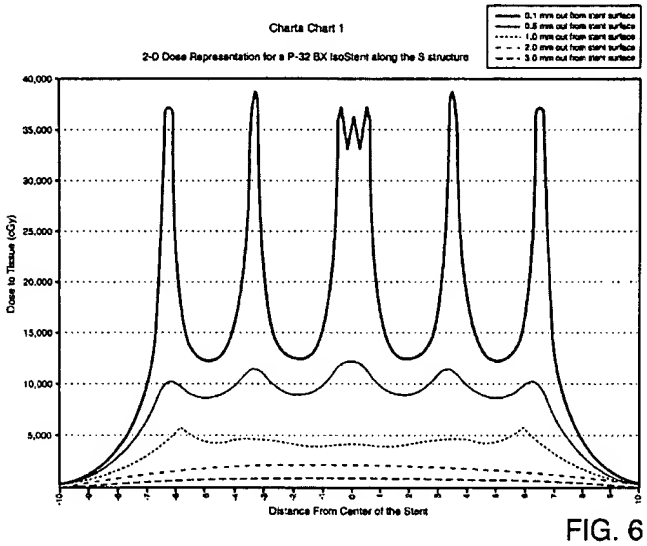

FIG. 6

Turnlund et al discloses Figure 6, above, illustrating Dose to Tissue vs. Distance From the Surface of Stent. Regarding independent claims 1, the Figure 6 illustrates the Turnlund et al device having an amount of therapeutic agent that gradually decreases along the length of the device.

Regarding independent claims 63 and 67, Figure 6 illustrates the Turnlund et al device have a more drug deposited in the middle region than the first or second end of the device.

Regarding claim 64 and 68 reciting the drug is deposited in a polymeric coating, applicant discloses in the specification on page 21, paragraph [0060] supporting methods for coating drug delivery sources with a particular drug are well known in the art. The Turnlund et al device is capable of performing the steps as recited in the method claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7, 10-12, 21-25, 27-32, 65, 66, 73, and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turnlund et al (U.S. Patent No. 6,296,603) and further in view of "The Pattern of restenosis and vascular remodeling after cold-end radioactive stent implantation" (P. Kay et al, European Heart Journal, 2001, volumn 22, issue #15, pages 1245-1247 & 1311-1317).

Turnlund et al discloses in Figures 3 a conventional stent-graft delivery system (28) comprising a radioisotope stent-graft (23) with a stent (20), the stent (20) comprising a central region (21), a proximal region (40), and a distal region (41). Turnlund et al discloses in Figure 6 illustrating both the proximal end and the distal end gradually decreasing but the charting in Figure 6 does not appears to suggest the ends gradually decrease a non-therapeutic level uniformly. P. Kay et al's article discloses a stent having radioactive mid-segment and non-radioactive proximal & distal ends (cold-ends). Therefore it would have been obvious to one skilled in the art to modify the Turnlund et al's stent to have proximal & distal ends with non-radioactive, as taught by the cited journal for purposes of preventing negative remodeling.

Regarding claims 10-12 and 27-29 reciting beta & gamma particles, see the Turnlund et al reference (column 19 lines 19-23).

Regarding claim 30, Turnlund et al discloses radiation dose ranges from about 1 Gy to about 600 Gy (column 18 lines 14-18).

Regarding claims 22, 32, Turnlund et al discloses in Figure 3 the therapeutic activities on the proximal/distal regions (40, 41) of stent (25), influencing the therapeutic activities past the proximal/distal regions (40, 41) since the proximal/distal edges (36, 37) of stent (25) overhang the ends of stent-graft (23).

Regarding claims 23 & 24, the Turnlund et al discloses in Figure 6 the uniformly decreasing the radioactive level from therapeutic level to non-therapeutic level. With regards to claim 23, the uniform level of radioactivity comprises a greater and longer longitudinal length than the gradient.

Regarding claim 25, it would have been obvious to one skilled in the art to variably decrease the radioactivity in the Turnlund et al's opposing ends of the stent for purposes of preventing or inhibiting excessive cell proliferation at those locations.

Regarding claim 65, the cited article discloses the stent having a radioactive middle segment and non-radioactive proximal and distal ends. Therefore it would have been obvious to one skilled in the art to maintain the Turnlund et al's proximal region (40) and distal region (41) non-radioactive or drug free, as taught by the cited article for the purposes of prevent negative remodeling.

Regarding claim 66 reciting the first or second end include a drug deposited thereon, the Turnlund et al discloses in Figure 6 illustrating the first or second end included a drug thereon.

Regarding claims 5, 73, 77-79 reciting the stent device having a drug specifics, particularly an anti-cell proliferation, the Turnlund et al device although discloses its application

with a proliferative drug, it does not discloses any structural specific in the device that would not performing using the cited drug. Therefore, one skilled in the art would have found the Turnlund et al would have practically utilize the Turnlund et al device with any drug compound(s) suitable including the anti-cell proliferation drug for treatment of the vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

C T Nguyen

Camtu Nguyen
November 14, 2007

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12/10/07